eele Laboratories

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DEC 1 9 2003

K033795

8. 510 (k) Summary

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Applicant/Manufacturer Name: eele Laboratories, LLC
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Bohemia, N.Y. 11716
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Name of Applicant/Contact: Robert Grasman (Phone extension; 106)
Signature of Applicant:
Dated: October 20, 2003

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Proposed Device

- Device Classification Name: Ultraviolet activator for polymerization
- Device Common Name: Dental Curing Light
- Trade/Proprietary Name: **PlasmaCure BXe**
- Regulation Number: 21 CFR 872.6070
- Regulatory Class: II
- Product Code: EBZ
- Review Advisory Committee: Dental

Substantial Equivalence

The **PlasmaCure BXe** addressed in this premarket notification, is substantially equivalent to the following commercially dental curing lights:

Device Name	Device/ Classification Name	Owner/Operator Applicant	510 (k) No.	Product Code	Reg. #
Rmo Plasma Curing Light	Activator, Ultraviolet, for Polymerization	Lokki Lasers Medicaux	K024374	EBZ	872.6070
Q-Lux Plasma 100 Light Cure Unit	Activator, Ultraviolet, for Polymerization	Rolence Enterprise Co., LTD	K001719	EBZ	872.6070
Optilux 501	Activator, Ultraviolet, for Polymerization	Kerr Corporation (Danbury)	K020091	EBZ	872.6070

Device Description

The **PlasmaCure BXe** is a device used for the polymerization of dental materials using blue light. It consists of a base unit and a cord connected hand piece. The molded plastic control unit (base unit) contains a power inlet receptacle for a detachable mains power cord, fuse holder and fuses, power supply & controller printed circuit board (control circuitry for lamp and cooling fan functions). The cord connected hand piece contains a printed circuit board, lamp reflector module assembly, optical filter assembly , fibertip insert and fiber optic tip that generates blue light energy having the wavelength range of approximately 385-495 nm. An external trigger switch (hand piece) activates the curing lamp. The emitted intensity and exposure time level depends on which type of *eeleCoolTip*™ is inserted in the hand piece and which key was last activated on the keypad of the base unit. The hand piece also has a removable and rotatable light shield that will protect the user when in operation.

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Statement of Indications for Use

The **PlasmaCure BXe** Curing Light is a source of illumination for curing dental restorative materials and is a source of illumination for tooth whitening activities performed in dentistry.

Device Testing Results and Conclusion

Bench testing was performed, which included biocompatibility, sterilization, packaging, and functionality to confirm that the **PlasmaCure BXe** is equivalent to the predicate devices. All bench testing results met specified requirements.

Summary of Technological Characteristics to Predicate Devices

- The Optilux 501 utilizes a halogen light source that is located in the plastic hand piece (handle) that also includes the optical filter assembly and fiber optic light guide. The light emanates from the light guide that is attached to the hand piece.

- The other comparable devices have their light source located in the control unit (box) and the light travels through a light pipe (conduit) and then the light guide. These devices are listed to demonstrate the "Plasma Arc" technology using a Xenon Arc Lamp.

- The PlasmaCure BXe has the light source (similar to Optilux 501) in the plastic hand piece (handle) as well as the optical filter assembly and fiber optic guide. Instead of having the light source in the control unit (box) as above, it is located in the hand piece.

Safety and Effectiveness Information Supporting the Substantial Equivalence

The **PlasmaCure BXe** complies with the following standards, practices, and guidance's:

Effectiveness: Independent Testing Facility test results for equivalence (non-clinical performance data).

The **PlasmaCure BXe** performed similar to other plasma arc lights, & polymerized faster than the halogen, laser, & LED lights evaluated at that time.

Safety: Pending Approval of UL 2601-1 including IEC 60601-1, CAN/CSA-C22.2 and evaluation to IEC 60601-1-4. In addition Immunity testing to EN50081-1 as well as Radiated and Conducted

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emissions testing to FCC 15 and EN55011 Class B limits to 1 GHz.

Independent Testing Facilities:

- Software development, verification, and validation process is also pending to ensure performance to specifications, Federal Regulations and user requirements.

- Environmental & Dynamic Testing including temperature, humidity, Mil-Std-810-E Method 514.4 category 1 and shock testing.

Conclusion

The intended use and technological features of the **PlasmaCure BXe** do not differ from the legally marketed predicate device(s). Both the **PlasmaCure BXe** and the predicate device(s) have the same materials and product design. The **PlasmaCure BXe** performs as well as or better than the predicate devices. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction. The subject device is substantially equivalent to the predicate devices with regard to intended use, indications, device characteristics, method of use, labeling, materials, and safety features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Eele Laboratories, LLC
Mr. Neil E Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K033795
Trade/Device Name: PlasmaCure
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class:
Product Code: EBZ
Dated: December 5, 2003
Received: December 5, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

5. Statement of Indications for Use

510(k) Number (if known): K033795

Device Name: **PlasmaCure BXe**

Indications For Use:

The **PlasmaCure BXe** Curing Light is a source of illumination for curing dental restorative materials and is a source of illumination for tooth whitening activities performed in dentistry.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033795

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)